OCT 27 2004

510 (k) Summary

K040518

Date Prepared [21 CFR 807.92(a)(1)]

March 1, 2004 **(Amended on 10/19/04)**

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o Select Fabricators Inc.
543 Long Hill Avenue
Shelton, CT 06484

Telephone: (203) 944-9320

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Select Fabricators. Select Fabricators Inc. submitted the Initial Establishment Registration form (FDA 2891) to FDA and is awaiting the assignment of a registration number.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]
Trade names are: Select Fabricators AgMed Tex© Wound Dressing
Common Name: Silver Nylon Contact Wound Dressing, Contact Wound Dressing, Anti-microbial Wound Dressing
Classification: Unclassified, Product Code: FRO

Predicate Device [21 CFR 807.92(a)(3)]

- Silverlon Wound Dressing – K981299

The subject devices have all of the same indications as the predicate device.
The material composition is identical. The subject device is offered in more of a variety of shapes and sizes including socks and self adhering bandages.
The sterilization method is the same as the predicate device.

The subject device exhibits 16%* silver and the predicate device exhibited 22% silver based on testing. The socks contain 6% silver (because the outside of the sock material does not have to be silver plated because it does not make contact with the patient).

- Polymem Silver Wound Dressing – K031307

The Polymem Silver Wound Dressing is a silver wound dressing that has received clearance for indications for use similar to the AgMed Tex™ and Silverlon.

Description of the Device [21 CFR 807.92(a)(4)]

The subject device is designed to contact the wound as a primary dressing and permit the passage of fluids. The dressing provides a protective moist environment for the wound and effective protection of against microbial contamination in the dressing. The subject device is an effective antimicrobial barrier dressing against the following organisms; Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, E. faecalis, Aspergillus niger and Escherichia coli.

The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in the subject device consists of a thin layer of metallic silver that provides effective protection of the dressing against microbial contamination.

The contact wound dressings are made of flexible, sterile, non-adherent fabric offered in 1 or 4 layers. The wound dressings will be initially available in the following sizes and varieties:

- 2"x2"
- 4"x4"
- 4"x8"
- 8"x8"
- 12"x48"
- 4" x 60" Elastic Wrap
- 8" x 108" Elastic Wrap
- Socks

The wound dressings are composed of a Nylon (polyamide) textile fiber substrate with metallic silver surface plating. The elastic wraps and socks also contain elastomer fiber. The wound dressings are made from MedTex P180 and Balingen. Both materials are silver plated Nylon (polyamide) textiles. The materials are identical with the exception that MedTex P180 is used for the stretch wraps and contains elastomer fiber. The raw material used on the device is silver nitrate. SWS 846 method 6010B (ICP) test method is used to determine purity. The purity of the silver in the dressing is 99.9% pure elemental silver, with a measured accuracy of 0.01%.

It is anticipated the AgMed Tex material will be offered in additional sizes including contact wound dressings (2"x2", 4"x4", 4"x8", 4"x12", 10"x12", 8"x8", 8"x16", 16"x16", 4"x24", 4"x72", 12"x48"), stretch wrap wound dressing of different sizes (including 4"x24", 4"x60", 4"x72", 4"x108", 8"x108"), strips (in sizes such as 1"x3"), self-adhering bandages, and socks.

The socks will use the same silver plated nylon textile material with elastomer fiber. The socks contain 6% silver.

The self adhering bandages will include the same silver plated nylon textile material along with an adhesive tape. The adhesive tape will be the Avery Dennison medical grade adhesive tape or similar. Only medical grade, biocompatible, and latex free

adhesive tapes will be used. Avery Dennison has these materials on file with FDA as a Drug Master File.

The subject devices will be packaged in a standard pre-formed peelable pouch designed to be used for medical packaging. The pouches will be labeled and packed in a labeled SBS box. SBS boxes are commonly used in medical device packaging. The SBS boxes will be packed into corrugated master shipping boxes. The peelable pouches and SBS boxes are compatible with radiation sterilization.

The subject devices are sterile single-use devices to be sterilized using a validated Gamma Radiation cycle affording an SAL of 10^{-6}. The devices are not to be reused, therefore cleaning and disinfection instructions are not applicable. The sterilization validation will be performed consistent with the ISO 11137 Standard – ***Sterilization of health care products – Requirements for validation and routine control – Radiation Sterilization.*** Method 1 will be employed to validate the sterilization process.

Products will be sterilized at one of the Isomedix facilities. After sterilization the products will be returned to Select Fabricators under quarantine and subjected to post sterility / final inspection prior to release and distribution.

Seal strength testing will be done on a routine basis during raw material receipt, in-process, and post-sterility processing. Seal strength testing (burst and creep to burst) will be performed using a TEST-A-PACK F100-2600 Seal Strength tester. Test will be applied per ASTM F-1140 or equivalent methods. The routine manufacturing inspection program will also consist of visual inspection for package integrity. The packaging validation will include Installation Qualification (IQ), Operation Qualification (OQ), and Performance Qualification (PQ). Inspections will be performed by SPC and/or ANSI/ASQ techniques.

It is recommended the patient examine the wound every 24 hours and change the dressing as needed. The use of petroleum based materials, materials with the ingredient Papain, and materials with high protein content are not recommended for use with AgMed Tex wound dressings as they may inactivate the silver.

The patients are warned against using the wearing the product during MR Imaging.

Intended Use [21 CFR 807.92(a)(5)]

Local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and stage I – IV dermal ulcers (vascular, venous, pressure, and diabetic).

Technological Characteristics [21 CFR 807.92(a)(6)]

Select Fabricators Inc. believes that the subject device is substantially equivalent to the predicate device. Both the subject device and predicate device are composed of similar silver plated nylon

textiles. Both the subject device and predicate device are sterilized using the same method and compliant with the same standards. The indications for use are identical.

Performance Data [21 CFR 807.92(b)(1)]

Silver has been safely used as an anti-microbial agent and in medical devices for many years. The device was found in laboratory tests to be effective in the reduction of several types of microorganisms including Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, E. faecalis, Aspergillus niger and Escherichia coli.

The subject device has been subject to ISO 10993-1biocompatibility testing (for the materials that contact the patient).

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Select Fabricators, Inc.
c/o Mr. Joseph M. Azary
Azary Technologies LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K040518
Trade/Device Name: Select Fabricators, Inc. AgMed Tex© Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 8, 2004
Received: September 9, 2004

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040518

Device Name: Select Fabricators Inc. AgMed Tex© Wound Dressing

Indications For Use:

Local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and stage I – IV dermal ulcers (vascular, venous, pressure, and diabetic).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040518